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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,654	03/29/2001	Kenichi Hosoya	10939/2012	6149

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	18

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,654	HOSOYA ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2002 and 25 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to the Amendment filed 18 October 2002 (Paper No. 16) and "Supplemental Reply" filed 25 November 2002 (Paper No. 17) filed in reply to the Non-Final Office Action mailed 20 May 2002 (Paper No. 14). Claims 1-14 were considered in Paper No. 14. Claims 1, 3, 5-7, 9-11, 13 and 14 were amended in Paper No. 16. Claims 1-14 are presently pending and under consideration.

Response to Amendment

35 U.S.C. § 102

Rejection of claims 1, 3, 6, 11 and 14 under 35 U.S.C. § 102(b) as anticipated by Greenwood *et al.* (1996) *J. Neuroimmunol.* 71:51-63 (hereinafter Greenwood *et al.*) is withdrawn in view of the amendments to the claims such that they are now limited to a cell and methods of producing said cell, wherein the cell is limited to a cell that does not comprise a heterologous antibiotic resistance gene. It is noted, however, that in the absence of this limitation the claims would stand rejected under 35 U.S.C. § 102(b) for reasons of record and set forth herein below.

35 U.S.C. § 103

Rejection of claims 1-3, 6, 7, 10, 11 and 14 under 35 U.S.C. § 103(a) as obvious over Rudland *et al.* and Greenwood *et al.* (U.S. Patent No. 6,090,624; hereinafter Greenwood *et al.* '624) in view of Roux *et al.* and Villalobous *et al.* is withdrawn in view of the amendments to the claims such that they are now limited to a cell and methods of producing said cell, wherein the cell is limited to a cell that does not comprise a heterologous antibiotic resistance gene.

Again, it is noted that in the absence of this limitation the claims would stand rejected for reasons of record and set forth herein below.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In Paper No. 16, claims 1, 3, 5-7, 9-11, 13 and 14 were amended to include the limitation, "wherein the cell is limited to a cell that does not comprise a heterologous antibiotic resistance gene". There is no support for this limitation in the application as originally filed.

Response to Arguments

35 U.S.C. § 102

As indicated above, cells comprising the claim limitations and that do not comprise a heterologous antibiotic resistance gene are not anticipated by the prior art. Therefore Applicant's arguments regarding the patentability of claims are acknowledged and accepted. However, in the absence of limitation to cells that do not comprise a heterologous antibiotic resistance gene the cells would be anticipated by the prior art. Although applicant has also added the limitation that

the cells are immortal at conditions below 39 °C, this limitation does not distinguish the claimed invention from the teachings of Greenwood *et al.* because, as conceded by applicant in the second full paragraph on page 6, the Greenwood *et al.* cells grow at 37 °C, which meets the limitation of below 39 °C.

35 U.S.C. § 103

Again, the patentability of cells comprising the claim limitations and that do not comprise a heterologous antibiotic resistance gene is accepted and acknowledged. However, in the absence of limitation to cells that do not comprise a heterologous antibiotic resistance gene the cells would not be patentable over the prior art. As above, the limitation that the cells are immortal at conditions below 39 °C does not distinguish the claimed invention from the teachings of the prior art because the transgenic animals of Rudland *et al.* comprise the tsA58 transgene, which is known in the art to produce cells that are immortal at below 39°C.

Applicant also argues that the instant claims are non-obvious over the cited art because "the cells of Rudland *et al.* require a cell type specific promoter (first full paragraph on page 9). This is not persuasive, however, because, although Rudland *et al.* teach specific embodiments comprising a cell type specific promoter, Rudland *et al.* does not in any way require a cell type specific promoter. As pointed out in the Office Action mailed 2 January 2002 (Paper No. 10), Greenwood *et al.* '624 provides the motivation to apply the teachings of Rudland *et al.* to the study of retinal cells. Given this motivation and the teachings of Greenwood *et al.* '624 which provide vectors capable of efficiently expressing the SV40 large T-antigen in rat retinal

endothelial cells (tenth full paragraph in column 3 and Example 2), the skilled artisan would know how to obtain expression in retinal endothelial cells.

Finally, Applicant argues that "it is not at all clear that one there is a reasonable chance of successfully producing the cells of the present invention, especially given that they first require the production of a transgenic animal. Iin [sic] addition, Rudland *et al.*'s requirement of inclusion of a cell-type specific promoter adds a level of complexity (and unpredictability) not required for production of Applicants' cells" (final paragraph on page 9). This argument is again based in part on the limitation of the claims to cells that do not comprise a heterologous resistance gene, which is acknowledged to be a non-obvious limitation. Beyond that, the skilled artisan would have a reasonable expectation of success in producing the cells of the instant invention because, as described above, the teachings of Greenwood *et al.* '624 are enabling for expression of the SV 40 large T-antigen in rat retinal endothelial cells, and the teachings of Rudland *et al.* are enabling for the production of a transgenic rat. Therefore, the claimed invention as a whole would have been obvious to the ordinary skilled artisan at the time the invention was filed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

dms
February 6, 2003